CLAIMS

1. A production process for a polymeric micelle charged therein with a water-scarcely soluble drug, comprising the steps of:

(A) dissolving a water-scarcely soluble drug and a block copolymer having a hydrophilic segment and a hydrophobic segment in a water non-miscible organic solvent to prepare an organic solution,

(B) mixing the resulting organic solution with an aqueous medium to form an oil-in-water (O/W) type emulsion,

(C) vaporizing and removing the above organic solvent from the resulting emulsion to form a polymeric micelle solution charged therein with the above drug, and

(D) subjecting the resulting polymeric micelle solution, if necessary, to supersonic treatment and ultrafiltration treatment.

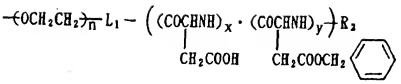
2. The production process as described in claim 1, wherein the hydrophilic segment is a segment comprising at least one selected from the group consisting of poly(ethylene oxide), poly(malic acid), poly(saccharide), poly(acrylic acid), poly(vinyl alcohol) and poly(vinylpyrrolidone).

3. The production process as described in claim 1 or 2, wherein the hydrophobic segment is a segment comprising at least one selected from the group consisting of poly(β-benzyl aspartate), poly(γ-benzyl glutamate), poly(β-alkyl aspartate), poly(lactide), poly(ε-caprolactone), poly(δ-valerolactone), poly(γ-butyrolactone) and poly(α-amino acid).

4. The production process as described in claim 1, wherein the hydrophilic segment comprises poly(ethylene oxide), and the hydrophobic segment is selected from the group consisting of poly(β-benzyl aspartate), poly(γ-benzyl glutamate), poly(β-benzyl aspartate-co-aspartic acid) and poly(γ-benzyl glutamate-co-glutamic acid).

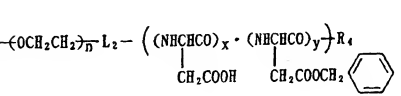
5. The production process as described in claim 1, wherein the block copolymer is represented by the following Formula (I) or

(II):



(I)

or



(II)

[wherein R_1 and R_3 each represent a hydrogen atom or a lower alkyl group; R_2 represents a hydrogen atom, a saturated or unsaturated C_1 to C_{29} aliphatic carbonyl group or an arylcarbonyl group; R_4 represents a hydroxyl group, a saturated or unsaturated C_1 to C_{30} aliphatic oxy group or an aryl-lower alkyloxy group; L_1 represents a linkage group selected from the group consisting of -NH-, -O- and -OCO-Z-NH- (wherein Z represents a C_1 to C_4 alkylene group); L_2 represents a linkage group selected from -OCO-Z-CO- and -NHCO-Z-CO- (wherein Z represents a C_1 to C_4 alkylene group); n represents an integer of 10 to 2500; x and y may be the same or different and represent integers the total of which is 10 to 300; x to y falls in a range of 3 : 1 to 0 : 100; and x and y each are present at random].

6. The production process as described in claim 5, wherein x to y in Formula (I) or (II) falls in a range of 7 : 3 to 1 : 3.

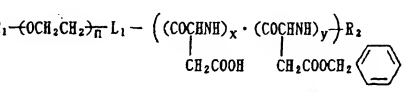
7. The production process as described in any of claims 1 to 6, wherein the drug and the block copolymer are used in a weight ratio of 1 : 10 to 3 : 10.

8. The production process as described in any of claims 1 to 7, wherein the water non-miscible organic solvent is at least one selected from the group consisting of chloroform, methylene chloride, toluene, xylene and n-hexane.

9. The production process as described in any of claims 1 to 8, wherein the drug is selected from the group consisting of paclitaxel,

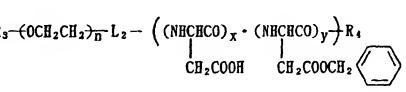
docetaxel and camptothecin and topotecan.

10. A composition comprising a polymeric micelle originating in a block copolymer charged therein with a drug, wherein the drug is a water-scarcely soluble drug; the block copolymer is represented by the following Formula (I) or (II):



(I)

or



(II)

[wherein R_1 and R_3 each represent a hydrogen atom or a lower alkyl group; R_2 represents a hydrogen atom, a saturated or unsaturated C_1 to C_{29} aliphatic carbonyl group or an arylcarbonyl group; R_4 represents a hydroxyl group, a saturated or unsaturated C_1 to C_{30} aliphatic oxy group or an aryl-lower alkyloxy group; L_1 represents a linkage group selected from the group consisting of -NH-, -O- and -OCO-Z-NH- (wherein Z represents a C_1 to C_4 alkylene group); L_2 represents a linkage group selected from -OCO-Z-CO- and -NHCO-Z-CO- (wherein Z represents a C_1 to C_4 alkylene group); n represents an integer of 10 to 2500; x and y may be the same or different and represent integers the total of which is 10 to 300; x to y falls in a range of 7 : 3 to 1 : 3; and x and y each are present at random]; a micelle solution prepared by dissolving or dispersing the above micelle in water can stably be maintained in a drug concentration of at least 3 mg per ml of the solution.

11. The composition as described in claim 10, wherein the drug is selected from the group consisting of paclitaxel, docetaxel, camptothecin and topotecan.

12. The composition as described in claim 10, wherein the drug

is paclitaxel and an analogue thereof.